(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 002 068**
A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 78101421.2

(22) Date of filing: 21.11.78

(51) Int. Cl.²: A 61 N 1/04, A 61 F 11/04

(30) Priority: 22.11.77 DK 5187/77

(43) Date of publication of application: 30.05.79 Bulletin 79/11

(84) Designated Contracting States: BE CH DE FR GB LU NL SE

(71) Applicant: Hansen, Carl Christian, Sødalleagade 114 B, DK-5000 Odense (DK)
(84) Designated Contracting States: BE CH DE FR GB LU NL SE

(71) Applicant: Lauridsen, Ole Mørk, Kærvej 13, DK-3520 Farum (DK)
(84) Designated Contracting States: BE CH DE FR GB LU NL SE

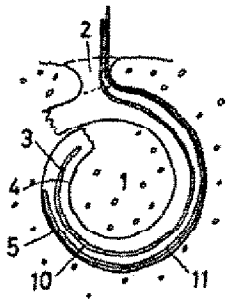
(72) Inventor: Hansen, Carl Christian, Sødalleagade 114 B, DK-5000 Odense (DK)
Inventor: Lauridsen, Ole Mørk, Kærvej 13, DK-3520 Farum (DK)

(74) Representative: Korn, Michael, Dipl.-Ing., Bahnstrasse 82, D-4000 Düsseldorf 1 (DE)

(54) Electrode for implantation into cochlea.

(57) An electrode for implantation into cochlea. The purpose is to establish electrical communication to the acoustic nerves of the human ear, substantially in the area of cochlea containing the acoustic nerves pertaining to that part of the audible spectrum which is relevant to the intelligibility of speech. The problem is, that an electrode inserted into cochlea certainly has made it possible to bring the patient in such a condition that she or he could interpret electrical signals supplied through the electrode as being sound but not as being intelligible speech.

The invention provides an electrode, which has two conditions of curvature, the one of which is temporary (10) and corresponds to the curvature in the middle of the particular turn of cochlea and the other one of which is permanent (11) and corresponds to the first position of the electrode in cochlea in which position it obtains an optimum contact to the acoustic nerves. The electrode of the invention further has means for changing the condition of curvature from the temporary one to the permanent one, when the electrode has been inserted into cochlea. The permanent condition of curvature whereas the temporary condition of curvature is established by means of a detachable or loosenable connection, which, until it is detached or loosened, maintains the temporary condition of curvature. A quick and reliable operation is made possible and the probability of obtaining a uniform communication over various frequency ranges along the cochlea is becoming great.



EP 0 002 068 A2

Electrode for implantation into cochlea.(II)

The present invention is related to an electrode for implantation into cochlea in order to establish electrical contact to the acoustic nerves of the human ear, the electrode comprising an insulating support member and supply lines to said nerves. Electrodes of this kind have been discussed be Martin Sonn. The prior art electrodes are disposed to be inserted through an opening to a patient's cochlea, whose internal ear is defective, in order to establish communication substantially in the area of cochlea, which is relevant to the intelligibility of speech, and accordingly the electrode has such an extension that it can reach through approximately two of the cochlea's two and a half turns. It has appeared, however, that the purpose has not been attained, in as much as it has certainly been possible to bring the patient in such a condition that she or he could interpret electrical signals supplied through the electrode as being sound but not as being intelligibel speech.

The present invention is based on the opinion that this fact is partly due to the circumstance that the prior art electrode, which during the insertion had to be guided in cochlea by the aid of the walls of cochlea, during this insertion happened to damage these walls and partly due to the circumstance that the electrode, even if the insertion was tolerably successfull, would not be able to position itself in cochlea in such a manner that the supplied signals was conducted selectively to the acoustic nerves for which they were destined for evoking in the brain those impressions which could cause it to percept the electrical signals as communicating, intelligible speech.

The present invention aims at avoiding the drawbacks associated with the prior art electrode. Accordingly, the present invention provides an electrode having two conditions of curvature, the one of which is temporary and corresponds to the curvature of the middle of the particular turn of cochlea, and the other one of which is permanent and

corresponds to the final position of the electrode in cochlea with the purpose of obtaining an optimum contact to the acoustic nerves, and means for changing the condition of curvature from the temporary one to the permanent one when the electrode has been inserted into cochlea. By the term "temporary" is meant "reckoned to the time until the electrode has been inserted into cochlea" and by the term "permanent" is meant "reckoned from the time after which the electrode has been inserted into cochlea". Thereby is achieved not only the possibility of a contactless insertion of the electrode into cochlea so that its walls are not further damaged, but additionally that the electrode, after being inserted into the desired turn or turns of cochlea, can be given such a required, increased or decreased curvature, that the electrode comes into cntact with the internal or the external wall of the cochlea duct and thereby happens to assume a constant position relative to the acoustic nerves throughout the various sections of the cochlea so that the nerve electrodes of the electrode, through which the electrical signals have to be transmitted to the proper acoustic nerves, can obtain over the entire electrode a constant and an optimum position relative to the acoustic nerves.

By an embodiment of an electrode according to the present invention the permanent condition of curvature is constituted by the electrode's natural condition of curvature whereas the temporary condition of curvature is established by means of a detachable connection, which, until it is detached or loosened, maintains the temporary condition of curvature. The advantage of this embodiment is that the electrode, when it is inserted into cochlea and when the detachable connection has been loosened, will be in a mechanically stressless condition, which it would be capable to assume for a long period of time without a tendency to change, that delicate adjustements of the electrode during the operation for insertion of the electrode will be unnecessary, which then permits a quick and reliable operation, and that the probability of obtaining a uniform communication over various frequency ranges along the cochlea becomes great.

In an embodiment of the electrode discussed above the mentioned detachable connection is thermo-detachable. Thereby is to understand that an elevation of temperature causes the detachable mechanical connection to cease. Such a heating can be carried out in many ways, for instance by diathermy, but it will be particularly advantageous if the thermo

detachment is carried out at a temperature being a few degrees centigrade below the body temperature, because the electrode then, shortly after its insertion into the cochlea turn, will be heated by the surrounding tissue to a temperature above the critical temperature to cause the detachment so that the electrode by own efforts so to speak finds its predetermined position in cochlea. By way of example, this could happen if the detachable connection according to the invention is made of wax. By wax is to be understood in this connection not only organic waxes but also other materials having a similar softening temperature and being inert to body tissue and fluids in the surroundings mentioned.

In a modified embodiment of an electrode of the kind mentioned the detachable connection is made of a material soluble or swellable in a fluid. According to the invention such a fluid may be the lymph in cochlea. Also this embodiment provides an electrode which shortly after its insertion into cochlea and without external influences assumes its predetermined position in cochlea. Yet another possibility of having an electrode comprising detachable connections, which are soluble, is according to the invention constituted by the employment of a mucus, e.g. a mucus from the patient herself or himself, which mucus is in a dried condition. This too could be caused to loosen itself by its contact with the lymph in cochlea.

Further it would be possible to provide an embodiment of the electrode according to the invention, in which the detachable connection is tearable. To this end it is necessary to employ mechanical forces, which in an embodiment of the electrode according to the invention are provided by the aid of a resilient hose inserted in the electrode, the hose containing a fluid, the pressure of which briefly can be increased to expand the hose and thereby tear up or break the detachable connection. Connections of this kind may be made by means of a light thermal welding, a linear welding or a spot welding involving a small welding area.

A particularly advantageous embodiment of an electrode according to the invention is obtained, if the detachable connection is positioned between two electrode surfaces, the one of which is carrying the electrode supply lines and the other one of which is carrying the nerve electrodes, and if said two surfaces are kept together along one of their longitudinal edges by means of an elastic connection formed by the insulating, supporting foil and along the other one of their longitudinal

edges by means of said detachable connection. By this embodiment is obtained that the surface including the electrode supply lines can be caused to lie inwardly or outwardly in cochlea assuming a shape, which roughly is similar to a cylindrical surface, and from this surface the nerve electrodes can fold or unfold after the loosening of the detachable connection to establish a contact with the partition in cochlea, in which the acoustic nerves are situated thereby obtaining the closest contact to these nerves. In this embodiment it may be desirable that the surface carrying the nerve electrodes has in its free edge a number of V-shaped notches to facilitate the elastic unfolding of the nerve electrodes from the surface carrying the signal or supply lines.

Among the possible embodiments of an electrode according to the invention is another one by which the detachable connection is made up of a layer or a body on one or both sides of the insulating support member, which layer or body is applied said member and is caused to become rigid, to harden or to solidify while the support member is forced to assume its temporary condition of curvature. After the insertion of the electrode into cochlea the detachable connection is softened thereby causing the temporary condition of curvature to cease. This embodiment is extremely simple in manufacture and design and therefore causes only minor possibilities of fault.

As an alternative to electrodes having a detachable connection it is possible to make embodiments by which the curvature of the electrode is continuously variable and fixable in said two conditions of curvature. Electrodes of this kind can be manufactured uniformly and may even be adapted to strongly varying working conditions, which may be of importance in situations, where it appears during an operation that special conditions exist such as cranial fractures or deformities, which require exceptional arrangements.

By an embodiment of an electrode of this kind a cord is provided within or on the insulating support member, the length or the tightening of which cord adjusts the curvature of the electrode, and which cord is maintained temporarily in a condition, in which it causes the temporary condition of curvature.

By another embodiment of an electrode of such kind the insulating support member of the electrode is formed like a tube having an oval cross-section and containing a fluid, the pressure of which defines the condition of curvature of the tube. Advantages of such an electrode are,

that it is extremely smooth and has a very little tendency to rupture the supply lines.

The invention will now be described in details below having reference to the accompanying drawings, in which

Figure 1 is a projection of a section through the center line in a single turn of a space in the cochlea during an operation for insertion of an electrode according to the invention,

Figure 2 is a plane, unfolded part of an embodiment of an electrode according to the invention,

Figure 3 is a schematic, perspective view of a form onto which is applied an electrode according to the invention,

Figure 4 is a schematic, perspective view of another form, around which an electrode according to the invention can be placed, while it is given a temporary condition of curvature, and

Figure 5 through 8 are cross-sections of further embodiments of an electrode according to the invention.

In figure 1 reference numeral 1 indicates a section in the cranium, in which an opening 2 has been provided, which opening leads to a turn of the cochlea. This turn contains three spaces and normally one would introduce the electrode into the lower space 3. In the wall between said space and the intermediate one is the basilar membrane, and the acoustic nerves extend from the brain to the core of cochlea and further to the field above the lower space. The lower space 3 has an internal wall 4 and an external wall 5 and forms a spiral. It is now possible to introduce the electrode according to the present invention through the opening 2. During the insertion the electrode has a curvature, which corresponds to the center line between the internal wall 4 and the external wall 5. This curvature is called "the temporary condition of curvature" 10. An electrode assuming the temporary condition of curvature 10 is in figure 1 illustrated immediately after its introduction. However, this position is not stable, as the electrode is floating, so to speak, in the lymph in the lower space. Therefore, a fixation of the electrode relative to the internal or external wall is important for obtaining, that the current field between the nerve electrodes over the entire length of the electrode can hit accurately and uniformly the desired zones having nerve endings. Accordingly, the electrode of the present invention has a permanent condition of curvature 11, which may have either a smaller radius of curvature or, as illustrated in figure 1, a greater radius of

curvature than the temporary one. Hence, the electrode will either nestle against the internal wall 4 or against the external wall 5 as showing in figure 1. Thereby, the electrode of the present invention has been given the combination of properties required for communication directly to the acoustic nerves: viz. it has to be so shaped that it can be introduced without damaging the walls of cochlea and in such manner that it is fixed relative to the nerve endings uniformly over the entire length of the electrode. It can be said that apparently there is a discrepancy between the requirement of the two properties mentioned, but the discrepancy has been brought to a conclusion by the inventive realization of the necessity of an electrode having two conditions of curvature, a temporary one 10 and a permanent one 11.

Consequently, the electrode according to the invention must include means for changing the curvature from the temporary condition of curvature 10 to the permanent one 11. It is possible to have two types of such means, the one of which is defined in the claims 2 through 12, whereas the other one is defined in the claims 13 through 15.

When describing the first one of these two types of means, the term "natural condition of curvature" is employed. Hereby is meant that curvature which an electrode will assume if it is not forced to assume another curvature, either as a result of an outer stress imposed by a band for example, which band is disposed to straighten the electrode or even to give it a curvature of opposite sense, or owing to the fact that the electrode temporarily has been given internal stresses, which changes temporarily the natural condition of curvature. In case of the first mentioned type of means the internal stresses are maintained temporarily by the aid of a detachable connection. When said detachable connection is broken the electrode assumes its permanent condition of curvature, viz. its natural condition of curvature.

In figure 2 is illustrated that part of the electrode according to the invention which carries the nerve electrodes 20 and which are to be positioned in cochlea. The remaining part of the electrode carries the connecting lines from the part illustrated to a signal generating apparatus. An electrode in this path of connections will usually have a base and a socket associated therewith permitting a separation between the patient and the signal apparatus. As neither the base, nor the socket nor the signal apparatus pertains the electrode according to the invention in another way than as necessary accessories, when the operated

patient is going to use the electrode, these parts have not been illustrated in the drawing and can be of conventional types. The nerve electrodes 20 are arranged in pairs in a manner well-known per se and a conductor or supply line 20 is leading to each nerve electrode. The nerve electrodes 20 as well as the conductor lines 21 are secured to an insulating support member 22 of a plastic foil having a suitable thickness, suitable properties of resilience and the property, which is so important for such kinds of electrodes, that the foil is inert to body tissue and fluids, which also is required for the material of the nerve electrode and the conductor line. Conductor lines and electrodes can be applied on the foil by the aid of any known method such as thin film technique. The outline of the electrode is stamped out, cut out or punched out also by employing well-known techniques. Separating each pair of electrodes 20 there is in the contour V-shaped notches 23 which protrude from one of the longitudinal edges. These notches serve to permit the required shape of double curvature, which the electrode must have in its temporary position as well as in its permanent position. Appropriately, the conductor lines 21 are covered by an insulating layer delimitting an external current field to the immediate proximity of the nerve electrodes 20.

Figure 3 illustrates a form or mandrel comprising two cylindrical members 30 and 31 respectively and therebetween a form member 32 of double curvature. The form of mandrel is disposed to be heated to a temperature above the softening temperature of the insulating support member 22. The form member 32 image the wall in cochlea at the position of the permanent placement of the electrode. By placing the electrode so that its insulating support member 22 and nerve electrodes 20 are contacting the form member 32 and subsequently cooling the form or mandrel, cf. figure 3, from a temperature above the softening temperature to below the solidifying temperature, the electrode is caused to assume its natural condition of curvature. It is to be understood from figure 3 that the nerve electrodes and the conductor lines are facing the form or mandrel whereas the insulating support member is illustrated as being transparent. Then the electrode is seen from the back of the printed circuit connections.

Subsequently, an electrode fashioned as mentioned above is wrapped around another shaping member, which is illustrated in figure 4. This member is shaped like a flat ring, which is cut open and wrung a little

out of plane so that its curvature corresponds to the temporary condition of curvature 10 illustrated in figure 1. Referring to figure 4, the cross-section of the ring is sharp-edged on the left-hand side 44 and round on the right-hand side 45. The electrode is arranged on the "ring" with its back facing the ring and the nerve electrodes 20 folded into the in-side 24 of the ring whereas the conductor side is on the out-side 42 of the ring. The circumference of the cross-section of the ring is a little shorter than the distance between the edge 24 of the insulating support member and the tips 25 of the nerve electrodes 2o. This has the effect that contacts between the electrode tips 25 and the edge 24 will be produced at the left-hand, sharp edge 24. It is at those contacts that the detachable connection is established in some of the embodiments of the invention.

As it appears from figure 4 the end of the ring, which is visible, has a little longer circumference than the other end, which is indicated partly in a dotted line. This design results in that the electrode can be pulled off the ring like a stocking after the detachable connections have been established..

By some of the embodiments the detachable connections are inserted between the edge 24 and the electrode tips 25 and by some other embodiments, in which use is made of wax or mucus, the detachable connections are best established by dipping or by spraying the connecting material while an auxiliary tool keeps the electrode members in position on the ring as discussed above, cf. figure 4.

An embodiment, by which the detachable connection is tearable, is illustrated in figure 5. By this embodiment the electrode is folded around an elongated hose 50, which is accessible from the outside, instead of around the ring. The one end of the hose 50 is given a curvature similar to that of the ring. Then it is possible by means of a dot-welding tool to provide tearable dot-weldings 51 between the nerve electrode side of the electrode and its conductor side and fairly close to the hose 5o. Thsi measure enables the hose 50 to tear up the dot-weldings by letting the hose expand resiliently by establishing a pressure in the interior of the hose.

By the embodiment defined in claim 12 the temporary condition of curvature is provided thereby, that an electrode, which has been given its permanent condition of curvature as described with reference to figure 3, is curved to its temporary condition of curvature 10 and in

this condition is applicated a layer or a body 60, cf. figure 6. This layer or body has in itself a form stability which is sufficient to secure the temporary condition of curvature 10, but when the detachable connection is detached the nerve electrode side 20 is unfolded with the center part 61 of the electrode serving as an elastic hinge, the condition of curvature thereby altering to the permanent one 11.

An embodiment of an electrode according to the invention can be given a continuously varying curvature if it is designed as indicated in figure 7. Figure 7 is a cross-section of such an electrode in a direction orthogonal to its longitudinal axis. In this figure the thickness of the insulating support member 70 is, for the sake of clarity, shown very exaggerated. The section is illustrated when having its permanent shape. To the back of the printed circuit is attached a pocket 71 and in the cavity 72 of the pocket is inserted a cord 73, one end of which is secured to the tip of the electrode. When the cord is tightened by pulling its opposite free end the condition of curvature of the electrode could be increased in order to establish an arbitrary, required temporary condition of curvature. Having inserted such a curved electrode into cochlea the pull of the cord is loosened whereby the electrode assumes its permanent curvature.

In figure 8 is illustrated a cross-section of an electrode shaped as a tube having an oval cross-section. The outer surface of this section carries nerve electrodes 20 and conductor lines 21 which are covered by an insulating layer 26. The electrode can by means of a thin film technique be provided on a thin foil, which subsequently is formed to a tube having a longitudinal seam. the tube can be arranged on a form or a mandrel of similar appearance as that illustrated in figure 4, but the sides 45 being rounded to the right-hand side as well as to the left-hand side. By heating to a temperature above the softening temperature of the foil and subsequently cooling to a temperature below the hardening temperature the tube is given its natural condition of curvature 11. A temporary change of the pressure within the tube 80 will give the tube its temporary condition of curvature 10 for insertion into cochlea. This embodiment of the electrode according to the invention is particularly advantageous in that it is only subjected to negligible, mechanical influences when being inserted into cochlea so that the risk of rupturing the conductor lines is reduced.

Patent Claims.

1. An electrode for implantation into cochlea for establishing an electrical contact to the acoustic nerves of the human ear, the electrode including an insulating support member and supply lines to said nerves, characterized by having two conditions of curvature (10 and 11), one of which is temporary and corresponds to the curvature in the middle of the particular turn of cochlea and the other one of which is permanent and corresponds to the final position of the electrode in cochlea with the purpose of obtaining an optimum contact to the acoustic nerves, and by the electrode having means for changing the condition of curvature from the temporary one (10) to the permanent one (11) when the electrode has been inserted into cochlea.

2. An electrode according to claim 1, characterized by the permanent condition of curvature (11) being the natural condition of curvature of the electrode, and by the temporary condition of curvture (10) being established by means of a detachable connection, which, until it is detached, maintains the temporary condition of curvature (10).

3. An electrode according to claim 2, characterized in that said detachable connection is thermo-detachable.

4. An electrode according to claim 3, characterized in that the thermo-detachment is carried out at a temperature, which is a few degrees centigrade below the body temperature.

5. An electrode according to claim 4, characterized in that said detachable connection is made of wax.

6. An electrode according to claim 2, characterized in that said detachable connection is made of a material soluble or swellable in a fluid.

7. An electrode according to claim 6, characterized in that said fluid is the lymph of cochlea.

8. An electrode according to claim 6, characterized in

that said detachable connection includes a dried mucus.

9. An electrode according to claim 2, characterized in that said detachable connection is tearable.

10. An electrode according to claim 9, characterized by a resilient hose (50) inserted in the electrode, said hose containing a fluid, the pressure of which can be raised briefly to expand the hose and thereby tear up said detachable connection.

11. An electrode according to claim 2, characterized in that said detachable connection is positioned between two electrode surfaces, the one of which is carrying the electrode supply lines and the other one of which is carrying the nerve electrodes, and in that said two surfaces are kept together along one of their longitudinal edges by means of an elastic connection formed by the insulating, supporting foil and along the other one of their longitudinal edges by means of said detachable connection.

12. An electrode according to claim 2, characterized in that said detachable connection is made up of a layer or a body (60) on one or both sides of the insulating support member, which layer or body is applied said member and caused to become rigid, to harden or to solidify while the support member is forced to assume its temporary condition of curvature (10).

13. An electrode according to claim 1, characterized by said curvature of the electrode being continuously variable and being fixable in said two conditions of curvature (10, 11).

14. An electrode according to claim 13, characterized in that a cord (73) is provided within or on the insulating support member, the length or the tightening of which cord adjusts the curvature of the electrode and which cord is maintained temporarily in a condition, in which it causes said temporary condition of curvature (10).

15. An electrode according to claim 13, characterized in that said insulating support member of the electrode is formed like

a tube having an oval cross-section and that said tube contains a fluid, the pressure of which defines the condition of curvature of said tube.

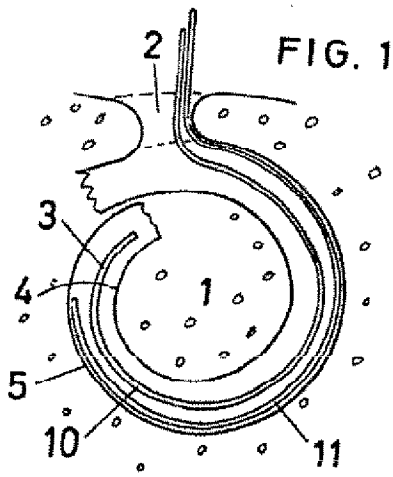


FIG. 1

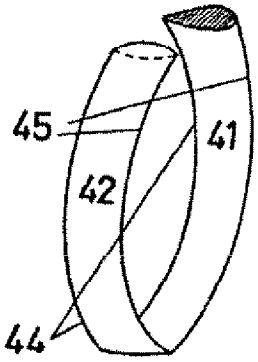


FIG. 4

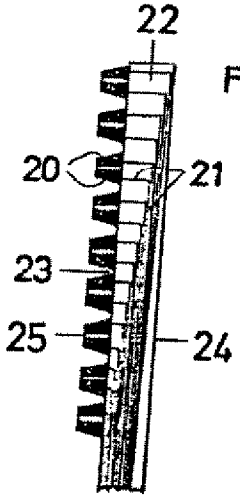


FIG. 2

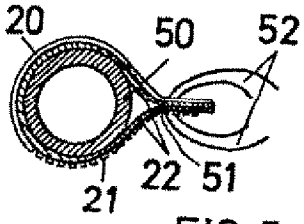


FIG. 5

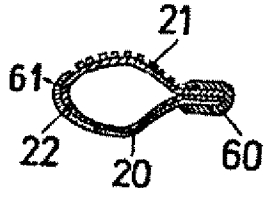


FIG. 6

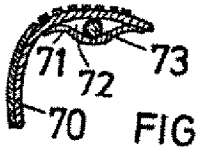


FIG. 7

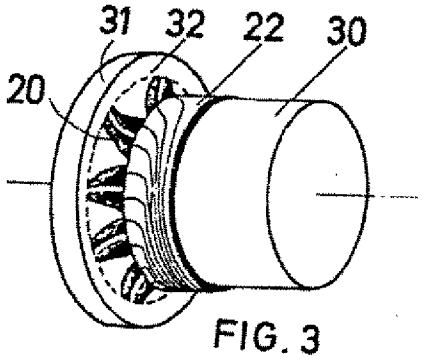


FIG. 3

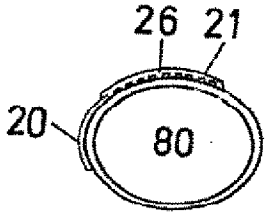


FIG. 8